IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVENTIS PHARMA S.A.,	)	
	)	
Plaintiff,	)	Civil Action No. _____
	)	
v.	)	
	)	
BAXTER HEALTHCARE CORP.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Aventis Pharma S.A. ("Aventis Pharma"), for its Complaint against Defendant Baxter Healthcare Corp. ("Baxter"), hereby states as follows.

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 5,565,427 ("the '427 patent"), arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq*. This action relates to Baxter's making, using, offering for sale, selling and importing into the United States of its ADVATE® product, which contains a stabilized solution with Factor VIII:C activity.

2. On April 11, 2003, A. Nattermann & Cie GmbH ("Nattermann") and Aventis Behring L.L.C. ("Aventis Behring") filed suit against Baxter in this Court, seeking a declaratory judgment that Baxter's imminent and intended manufacture, use, offering for sale, selling or importing into the United States of its ADVATE® product would constitute infringement of the '427 patent. During discovery, Baxter produced certain information that it had refused to provide absent litigation. Nattermann, the owner of the '427 patent at that time, provided this new information to the U.S. Patent and Trademark Office ("PTO") and requested that the PTO

reexamine the '427 patent in view of this information. Due to the reexamination, the parties stipulated to a dismissal of the litigation without prejudice, which the Court entered on November 4, 2003. In that stipulation, the parties agreed to re-file the action in this same Court once the PTO completed its reexamination of the '427 patent. The reexamination process is now over, and, accordingly, Aventis Pharma brings the present action.

THE PARTIES

3. Aventis Pharma is a corporation organized under the laws of France with its corporate headquarters at 20, avenue Raymond Aron, 92160 Antony, France.

4. Upon information and belief, Baxter is a Delaware Corporation having its corporate offices at One Baxter Parkway, Deerfield, Illinois 60015.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has jurisdiction over Baxter because, on information and belief, Baxter is a Delaware corporation and purposefully has conducted and continues to conduct business in this judicial district, has placed the infringing product ADVATE® in the stream of commerce knowing and intending that this judicial district was and is a likely destination of that product, has caused injury to Aventis Pharma in this judicial district, and has committed acts of infringement in this judicial district. In addition, Baxter stipulated to the Court's jurisdiction over this matter in the prior related action.

7. Upon information and belief, this Court has personal jurisdiction over Baxter. Indeed, Baxter stipulated to this Court's exercise of personal jurisdiction over Baxter in the prior related action.

8. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and 1400(b). Indeed, Baxter stipulated to venue in the prior related action.

FIRST COUNT FOR PATENT INFRINGEMENT

9. The PTO duly and legally issued the '427 patent, entitled "Stabilized Factor VIII Preparations," to Behringwerke Aktiengesellschaft, as assignee of inventor Wilfried Freudenberg, on October 15, 1996. A true and correct copy of the '427 patent is attached as Exhibit A.

10. Behringwerke Aktiengesellschaft merged with Hoechst Aktiengesellschaft, and Hoechst Aktiengesellschaft subsequently assigned the '427 patent to Centeon Pharma GmbH, which in turn became Aventis Behring GmbH upon the merger of Hoechst and Rhone Poulenc to form Aventis. Aventis Behring GmbH subsequently assigned the rights to the '427 patent to Nattermann.

11. Aventis Pharma is the present owner of the '427 patent as a result of an assignment from Nattermann.

12. On July 23, 2002, the PTO issued a Reexamination Certificate. A true and correct copy of the first Reexamination Certificate is attached as Exhibit B.

13. On October 10, 2006, the PTO issued a second Reexamination Certificate. A true and correct copy of the second Reexamination Certificate is attached as Exhibit C.

14. The '427 patent discloses and claims, *inter alia*, stabilized solutions with factor VIII:C activity and methods of manufacturing such stabilized solutions.

15. Baxter has knowledge of the '427 patent and of the infringement allegations regarding Baxter's ADVATE® product as a result of the earlier action and the events preceding that action.

16. Based on information available from the United States Food and Drug Administration's ("FDA") Web site (www.fda.gov), the FDA granted Baxter approval on July 25, 2003, to manufacture, use, offer to sell and sell in the United States its "antihemophilic Factor VIII (Recombinant), plasma/albumin free" product under the trademark ADVATE®.

17. On information and belief, Baxter began selling and offering for sale its ADVATE® product in this judicial district and elsewhere in the United States in August of 2003.

18. Baxter's making, using, offering for sale, selling and importing into the United States of its ADVATE® product infringes one or more claims of the '427 patent under 35 U.S.C. § 271.

DAMAGES AND OTHER HARM SUFFERED BY AVENTIS PHARMA

19. Baxter's acts of infringement have damaged Aventis Pharma in an amount not yet determined and will continue to damage Aventis Pharma in the future.

20. Upon information and belief, Baxter's acts of infringement constitute willful infringement, entitling Aventis Pharma to treble damages and attorneys' fees.

PRAYER FOR RELIEF

WHEREFORE, Aventis Pharma respectfully requests that the Court enter judgment in its favor, and against Baxter, on the patent infringement claim set forth above, and that it award the following relief:

(1) find that Baxter infringes at least one claim of the '427 patent by its making, using, offering for sale, selling and importing into the United States of its ADVATE® product;

(2) find that Baxter's infringement has been willful;

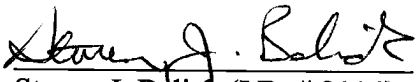
(3) award Aventis Pharma damages adequate to compensate it for the aforesaid infringement, together with prejudgment interest thereon;

(4) treble damages under 35 U.S.C. § 284 because of Baxter's willful infringement;

(5) award Aventis Pharma its reasonable attorneys' fees and the costs of this action under 35 U.S.C. § 285; and

(6) award Aventis Pharma any further and additional relief as this Court deems just and proper.

ASHBY & GEDDES



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174152.1

EXHIBIT A

US005565427A

United States Patent [19]

Freudenberg

[11] Patent Number: 5,565,427

[45] Date of Patent: Oct. 15, 1996

[54] **STABILIZED FACTOR VIII PREPARATIONS**

[75] Inventor: **Wilfried Freudenberg**, Cölbe-Schönstadt, Germany

[73] Assignee: **Behringwerke Aktiengesellschaft**, Marburg, Germany

[21] Appl. No.: **235,241**

[22] Filed: **Apr. 29, 1994**

Related U.S. Application Data

[63] Continuation of Ser. No. 82,911, Jun. 29, 1993, abandoned, which is a continuation of Ser. No. 864,610, Apr. 7, 1992, abandoned.

[30] **Foreign Application Priority Data**

Apr. 9, 1991 [DE] Germany 41 11 393.4

[51] **Int. Cl.**[6] **A61K 35/14**; C07K 1/00; C07K 14/00

[52] **U.S. Cl.** **514/12**; 514/21; 530/383

[58] **Field of Search** 530/383; 514/12, 514/21

[56] **References Cited**

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Meyers, R. et al., "Large Scale Preparation of a Highly Purified Solvent–Detergent Treated Factor VIII Concentrate," VOX Sang. vol. 60, pp. 141–147 (1991).

Primary Examiner—Elizabeth C. Weimar
Assistant Examiner—P. Lynn Touzeau
Attorney, Agent, or Firm—Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.

[57] **ABSTRACT**

The invention relates to stabilized solutions with F VIII coagulation activity, to a process for the preparation thereof and to the use thereof.

13 Claims, No Drawings

STABILIZED FACTOR VIII PREPARATIONS

This application is a continuation of application Ser. No. 08/082,911 filed Jun. 29, 1993, now abandoned, which is a continuation of application Ser. No. 07/864,610, filed Apr. 7, 1992, abandoned.

The invention relates to stabilized solutions with F VIII coagulation activity, to a process for the preparation thereof and to the use thereof.

Coagulation factor VIII:C (F VIII:C) is a plasma protein and essential for the process of the intrinsic pathway of blood coagulation. A deficiency or a defect in blood coagulation factor VIII:C results in a life-threatening disturbance of blood coagulation, hemophilia A. Concentrates of F VIII:C from human plasma or genetically engineered F VIII:C are employed for the therapy of hemophilia A.

These F VIII products differ in respect of their purity, i.e. the presence of proteins which do not have coagulation activity in addition to the active substance F VIII:C. A F VIII which has more than 1000 U/mg before stabilization with albumin is called very high purity F VIII (VHP F VIII:C) (WHO, Expert Committee on Biological Standardization).

Such VHP F VIII:C have potential advantages in the treatment of hemophilia. These are the freedom from viruses and a very small content of foreign protein, which means less stress on the immune system of the patients after administration of these concentrates. The advantage which is possible per se, of less stress on the immune system of a hemophiliac patient by administration of a F VIII preparation with high specific activity, is, however, cancelled out by addition of high albumin concentrations to the highly purified product in order to stabilize the VHP F VIII. This addition of albumin means that the highly purified F VIII concentrates reach specific activities of only 3–10 U/mg in the final formulation thereof.

Although addition of albumin entails only a slight risk with respect to virus safety, it has to be borne in mind, however, that with albumin whose purity averages 95% once again unwanted concomitant proteins are administered to the patient and may stress his immune system.

High purity F VIII product: which dispense with addition of albumin for stabilization of F VIII are known (Schwinn, Smith & Wolter, Drug. Res. 39 (1989), 1302). These products reach specific activities of about 100 U/mg of protein. Based on a maximum achievable F VIII activity of about 5000 U/mg, this means that only about 2% of the protein content of these preparations comprises F VIII:C protein. It is to be assumed in this case that this 2% F VIII:C is stabilized by the 98% concomitant proteins, because a large part of these concomitant proteins is likely to comprise yon Willebrand Factor (vWF). It is known that von Willebrand Factor has a stabilizing action on F VIII:C.

The situation is different with very high purity products which have specific activities which, before albumin stabilization, are usually more than 25 times higher than for high purity products, and the vWF content thereof is very low. This low vWF content is no longer able to ensure adequate F VIII stabilization so that the F VIII activity in solutions which are not stabilized with albumin rapidly decreases.

The object of the present invention was therefore to provide a process which makes it possible to prepare a highly concentrated, physiologically tolerated solution of a VHP F VIII:C product, which solution requires no addition of proteins for stabilization.

This object is achieved according to the invention by adding an amino acid or one of its salts, derivatives or homologs to a VHP F VIII:C preparation. It is possible to add L- and/or D-amino acids. Particular suitable are arginine, lysine, ornithine, guanidinoacetic acid or others whose common feature is a basic group in the form of an amino and/or guanidino group.

The invention therefore relates to a solution with factor VIII:C activity containing an amino acid or one of its salts or derivatives and, ;here appropriate, a detergent or an organic polymer.

Preferred embodiments are:

a solution wherein the amino acid is a natural amino acid;

a solution wherein the amino acid is a basic amino acid;

a solution which contains arginine and glycine;

a solution wherein the concentration of the amino acid is 0.001 to 1 mol/l;

a solution which additionally contains an organic polymer or a nonionic detergent;

a solution wherein the F VIII:C activity derives from human factor VIII in its form which occurs in plasma or from a genetically engineered factor VIII:C or a derivative of these;

and a solution wherein the specific F VIII:C activity is at least 1000 IU/mg.

Improved stabilization is achieved by combination of amino acids or their derivatives or with a nonionic detergent such as ®Polysorbate 20 or ®Polysorbate 80 or an organic polymer such as polyethylene glycol 1500.

A combination of the amino acids arginine and glycine, preferably 0.01 to 1 mol/l, with the nonionic detergent ®Tween 80, preferably 0.001 to 0.5% (v/v), and with a neutral sugar such as sucrose, preferably 0.1 to 10%, has proven particularly suitable for the preparation of a stable, albumin-free VHP F VIII:C solution.

The pH of a solution of this type is adjusted to between pH 5.5 and 8.5, preferably between pH 6.5 and 7.5, by means of an organic acid, preferably 10% strength acetic acid.

The invention also relates to a pharmaceutical containing a solution of this type. Besides a solution of this type, this pharmaceutical can contain customary, pharmaceutically compatible, stabilizing and/or buffering substances, especially a carbohydrate.

The invention likewise relates to a process for the preparation of a solution of this type, wherein an amino acid or one of its salts or derivatives and, where appropriate, an organic polymer or a detergent is added to a solution with factor VIII:C activity.

The advantageous effect of the process according to the invention can be shown, for example, for a F VIII:C preparation which has been purified by chromatography on monoclonal anti-F VIII:C antibodies, it being possible for the F VIII:C to be both obtained from plasma and genetically engineered, for example in CHO (Chinese Hamster Ovary) cells. This entails, for example, equal parts of a solution of the abovementioned substances being added to the eluate from the monoclonal antibody column, and subsequently the latter being dialyzed against this solution. The stabilized F VIII:C preparation obtained in this way can be sterilized by filtration and bottled with low method-related losses. A lyophilizate of this preparation obtained in this way has unchanged high F VIII:C activities after dissolution.

It is possible with the process according to the invention to prepare a VHP F VIII:C preparation whose specific volume-based activity is at least 200 IU/ml, with a specific activity of more than 2000 IU/mg. This concentration ensures that there are no problems with manipulation owing to the need to administer small volumes.

A preparation of this type does not need further stabilization by proteins, which avoids the risk of virus contamination. At the same time, the reduction in the high protein load means a considerable reduction in the stress on the immune system of the patient due to the addition of the albumin, which is unnecessary for the medicinal action, and of the unwanted impurities contained therein.

Since physiologically tolerated substances are added for the stabilization, no intolerance reactions occur on administration of the solution according to the invention.

EXAMPLE 1

Two VHP F VIII:C preparations were prepared, both by means of affinity chromatography on monoclonal anti-vWF Ig (method of Fulcher & Zimmermann PNAS (1982), 79, 1649) and dissociation of the vWF/F VIII:C complex by solution with a $CaCl_2$ concentration of 300 mM in 0.1 M acetate, 0.1 M lysine, pH 6.8 (eluate I), and by means of chromatography on monoclonal anti-F VIII:C Ig and elution of the F VIII:C by 50% ethylene glycol in 0.1 M acetate, 0.1 M lysine, pH 6.8 (eluate II). The specific F VIII:C activity determined in eluate I was 2500 IU/mg and 419 IU/ml, and in eluate II was 3280 IU/mg and 454 IU/ml. The two eluates were divided in each case. To one portion in each case was added in the ratio 1:1 by volume a 1% strength human albumin solution in 0.75% sucrose, 3% glycine and 0.1 mol/l NaCl (eluate I_{HSA}, eluate II_{HSA}). The stabilization buffer (0.75% sucrose, 3% glycine, 3% arginine, 0.05% ®Tween 80, pH 6.8) was likewise added 1:1 to the other half in each case (eluate I_S, eluate II_S). The albumin-containing samples were dialyzed against 0.75% sucrose, 3% glycine, 0.1 mol/l NaCl, pH 6.8, and the others against stabilization buffer. Dialysis was carried out at 4° C. for 16 hours with 1000-fold volume change. The F VIII:C activities were measured before and after the dialysis. Table 1 shows the F VIII:C activity in % relative to the total F VIII:C activity in the particular sample before dialysis.

TABLE 1

Eluate I_{HSA}	Eluate I_S	Eluate II_{HSA}	Eluate II_S
92	94	94	93

The results show that stabilization of the VHP F VIII:C eluates by means of the stabilization solution according to the invention is achieved irrespective of the preparation method and to the same extent as by addition of albumin.

EXAMPLE 2

An F VIII:C eluate with a specific F VIII:C activity of 3860 IU/mg of protein and 462 IU/ml was obtained after immunoaffinity chromatography on monoclonal anti-F VIII:C antibodies. Various stabilization solutions were added to this in the ratio 1:1 by volume, and it was dialyzed against the relevant stabilization solution as described in Example 1. A pH of 6.8 was adjusted in all solutions where appropriate with 10% acetic acid.

The following stabilization solutions were employed:

I. 0.75% sucrose, 0.4 M glycine, 0.15 M sodium chloride

II. 0.01M sodium citrate, 0.08 M glycine, 0.016 M lysine, 0.0025 M calcium chloride, 0.4 M sodium chloride

III. 1% sucrose, 0.14 M arginine, 0.1M sodium chloride

IV. 1% sucrose, 0.4 M glycine, 0.14 M arginine, 0.1M sodium chloride, 0.05% Tween 80

The F VIII:C activity was determined before and after the dialysis. In Table 2 the F VIII:C activity after dialysis is plotted in % relative to the relevant activity before dialysis.

TABLE 2

Mixture	I	II	III	IV
F VIII:C activity after dialysis for 16 hours	39.3%	35.1%	82.4%	96.2%

The solutions employed under I and II can be employed for the stabilization of albumin-free HP F VIII products with specific F VIII:C activities of 100–200 IU/mg, dispensing with addition of albumin. Solutions III and IV are suitable for stabilization of VHP F VIII preparations with specific F VIII:C activities greater than 1000 IU/mg.

I claim:

1. A stabilized solution with factor VIII:C activity containing factor VIII:C, an amino acid or one of its salts or homologs and a detergent or an organic polymer, wherein the specific factor VIII:C activity is at least 1000 IU/mg.

2. A solution as claimed in claim **1**, wherein the amino acid is a natural amino acid.

3. A solution as claimed in claim **1**, wherein the amino acid is a basic amino acid.

4. A solution as claimed in claim **1**, which contains arginine and glycine.

5. A solution as claimed in claim **1**, wherein the concentration of the amino acid is 0.001 to 1 mol/l.

6. A solution as claimed in claim **1**, which contains an organic polymer or a nonionic detergent.

7. A solution as claimed in claim **1**, wherein the F VIII:C activity is derived (a) from human factor VIII in its form which occurs in plasma or (b) from a genetically engineered factor VIII:C or (C) from a homolog of (a) or (b).

8. A pharmaceutical containing a solution as claimed in claim **1**.

9. A pharmaceutical as claimed in claim **8** further containing pharmaceutically compatible, stabilizing or buffering substances.

10. A pharmaceutical as claimed in claim **9**, which contains a carbohydrate.

11. A process for the preparation of a stable factor VIII:C solution which comprises adding an amino acid or one of its salts or homologs and an organic polymer or a detergent to a solution with factor VII I:C activity, wherein the specific factor VIII:C activity is at least 1000 IU/mg.

12. A stabilized solution as claimed in claim **1** containing an amino acid or one of its salts or homologs and an organic polymer, wherein the amino acid is arginine or glycine and the organic polymer is polyethylene glycol.

13. A stabilized solution as claimed in claim **1** containing an amino acid or one of its salts or homologs and a detergent, wherein the amino acid is arginine or glycine and the detergent is polyoxyethylene sorbitan mono-oleate.

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EXHIBIT B

US005565427C1

(12) REEXAMINATION CERTIFICATE (4618th)

United States Patent
Freudenberg

(10) Number: US 5,565,427 C1
(45) Certificate Issued: Jul. 23, 2002

(54) STABILIZED FACTOR VIII PREPARATIONS

(75) Inventor: Wilfried Freudenberg, Cölbe-Schönstadt (DE)

(73) Assignee: Aventis Behring GmbH, Marburg (DE)

Reexamination Request:
No. 90/006,025, May 30, 2001

Reexamination Certificate for:

Patent No.:	5,565,427
Issued:	Oct. 15, 1996
Appl. No.:	08/235,241
Filed:	Apr. 29, 1994

Certificate of Correction issued Feb. 18, 1997.

Related U.S. Application Data

(63) Continuation of application No. 08/082,911, filed on Jun. 29, 1993, now abandoned, which is a continuation of application No. 07/864,610, filed on Apr. 7, 1992, now abandoned.

(30) **Foreign Application Priority Data**

Apr. 9, 1991 (DE) 41 11 393

(51) **Int. Cl.**[7] A61K 35/14; C07K 1/00; C07K 14/00

(52) **U.S. Cl.** 514/12; 514/21; 530/383

(58) **Field of Search** 514/12, 21; 530/383

(56) **References Cited**

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Primary Examiner—Jeffrey E. Russel

(57) **ABSTRACT**

The invention relates to stabilized solutions with F VIII coagulation activity, to a process for the preparation thereof and to the use thereof.

REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

NO AMENDMENTS HAVE BEEN MADE TO THE PATENT

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

The patentability of claims 1–13 is confirmed.

* * * * *

EXHIBIT C

US005565427C2

(12) EX PARTE REEXAMINATION CERTIFICATE (5561st)

United States Patent
Freudenberg

(10) Number: US 5,565,427 C2
(45) Certificate Issued: Oct. 10, 2006

(54) **STABILIZED FACTOR VIII PREPARATIONS**

(75) Inventor: **Wilfried Freudenberg**, Cölbe-Schönstadt (DE)

(73) Assignee: **A. Nattermann und Cie GmbH**, Cologne (DE)

Reexamination Request:
No. 90/006.823, Oct. 21, 2003

Reexamination Certificate for:
Patent No.: **5,565,427**
Issued: **Oct. 15, 1996**
Appl. No.: **08/235,241**
Filed: **Apr. 29, 1994**

Reexamination Certificate C1 5,565,427 issued Jul. 23, 2002

Certificate of Correction issued Feb. 18, 1997.

Related U.S. Application Data

(63) Continuation of application No. 08/082,911, filed on Jun. 29, 1993, now abandoned, which is a continuation of application No. 07/864,610, filed on Apr. 7, 1992, now abandoned.

(30) **Foreign Application Priority Data**

Apr. 9, 1991 (DE) 41 11 393

(51) **Int. Cl.**
A61K 35/14 (2006.01)
C07K 1/00 (2006.01)
C07K 14/00 (2006.01)

(52) **U.S. Cl.** **514/12**; 514/21; 530/383
(58) **Field of Classification Search** 514/12, 514/21; 530/383
See application file for complete search history.

(56) **References Cited**

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Nov. 21, 2003, Plaintiff's Opposition to Defendant's Motion for leave to file amended answer and counterclaims.
Mar. 22, 2004, Transcript of Motion before Judge Brody to stay or dismiss.
Mar. 30, 2004, ORDER.
Mar. 30, 2004, Bayer's subpoena of Finnegan–Henderson of documents in attached Schedule A.
Mar. 30, 2004, Defendant's Revised Notice of Deposition of A. Nattermann & Cie GmbH, Aventis Behring L.L.C. & Aventis Behring GmbH Pursuant to Rule 30(b)(6).
Apr. 2, 2004, Notice of Service of Subpoena on Finnegan–Henderson and Subpoena itself.

(Continued)

Primary Examiner—Kathleen M. Kerr

(57) **ABSTRACT**

The invention relates to stabilized solutions with F VIII coagulation activity, to a process for the preparation thereof and to the use thereof.

OTHER PUBLICATIONS

May 3, 2004, Letter from T. Donaldson to T. Poche attaching Plaintiffs' objections and responses to Bayer's Mar. 30, 2004 Subpoena of Finnegan Henderson.
May 8, 2004, Order of May 8, 2004.
May 13, 2004, Order that Defendants' motion for summary judgment is DENIED without prejudice.
Jun. 1, 2004, ORDER memorializing parties agreement to complete depositions on or before Oct. 15, 2004.
Jun. 4, 2004, ORDER stating that Plaintiff's Motion to Stay and Plaintiff's Motion for Discovery are Denied as moot.
Sep. 27, 2004, Letter attaching copies of Subpoena of D. Farb, Notice of Services of Subpoena, Defendants' Notice of Deposition of Farb.
Sep. 27, 2004, Letter stating that Finnegan will be representing Dr. D. Farb at his deposition and will accept service on his behalf.
Sep. 28, 2004, Letter from T. Donaldson to T. Poche.
Oct. 21, 2004, Transcript of teleconference between Bayer, Aventis and Judge Brody re deposition of Dr. Freudenberg.
Feb. 16, 2005, Letter to Judge Brody.
Feb. 24, 2005, Letter to Judge Brody.
Mar. 4, 2005, Letter to the Court.
Mar. 10, 2005, Letter to the Court.
Mar. 11, 2005, Letter to Judge Brody.
Mar. 15, 2005, Letter to Judge Brody.
Mar. 16, 2005, Letter to Judge Brody.
Mar. 16, 2005, Copy of ORDER maintaining current stay pending the reexamination by the USPTO and requiring that parties keep the Court updated on its progress.
Derwent Abstract for WO 90/05140.
I. Scharrer, "Current status of a recombinant antihemophilic factor VIII clinical trial organized by Baxter," *Ann. Hematology*, 63: 172–176 (1991).
Order Granting Plaintiff's Motion for Discovery Under FED. R. CIV. P. 56(f).
Motion for Discovery Under FED. R. CIV. P. 56(f) on behalf of Plaintiffs filed Nov. 24, 2003.
Redacted Copy of Plaintiff's Memorandum in Support of Motion for Discovery Under FED. R. CIV. P. 56(f) filed Nov. 24, 2003, with attached Exhibits 1–16.
Order Denying Bayer's Motion for Summary Judgment of Noninfringement.
Redacted copy of Plaintiff's Opposition to Defendant's Motion for Summary Judgment of Noninfringement filed Nov. 24, 2003, with attached Exhibits 1–9.
Order Dismissing All Claims and Counterclaims Without Prejudice.
Order Staying Any Further Proceedings Pending Outcome of Reexamination of U.S. Pat. No. 5,565,427.
Plaintiffs' Memorandum of Law in Support of Its Motion to Dismiss All Claims and Counterclaims Without Prejudice or, in the Alternative, Stay Proceedings Pending Reexamination of U.S. Pat. No. 5,565,427 (Exhibits 1–10) filed Jan. 16, 2004.
Plaintiff's Answer to First Amended Counterclaims, filed Dec. 23, 2003.
Transcript of Dec. 1, 2003, hearing before the Honorable Anita B. Brody in Civil Action No. 03–2268 in the United States District Court for the Eastern District of Pennsylvania.
Bayer's Opposition to Plaintiffs' Motion to Dismiss All Claims and Counterclaims Without Prejudice or, in the Alternative, Stay Proceedings Pending Reexamination of U.S. Pat. No. 5,565,427 (with Exhibits), filed Jan. 30, 2004.
Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion For a Rule 54(b) Declaratory Judgment Regarding Aventis Behring's State Court Action (with Exhibits), filed Feb. 9, 2004.
Plaintiffs' Reply Memorandum of Law in Support of its Motion to Dismiss All Claims and Counterclaims Without Prejudice or, in the Alternative, Stay Proceedings Pending Reexamination of U.S. Pat. No. 5,565,427 (with Exhibits), filed Feb. 13, 2004.
Defendants' Reply to Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion For Rule 54(b) Declaratory Judgment Regarding Aventis Behring's State Court Action (with Exhibits), filed Feb. 16, 2003.
Order dated Feb. 19, 2004 in Civ. A. No. 03–2268 (*Nattermann* v. *Bayer* litigation).
Letter from Bayer's counsel to Honorable Anita B. Brody regarding Protective Order (with Exhibits) dated Mar. 12, 2004.
Letter from Nattermann's counsel to Honorable Anita B. Brody regarding Protective Order dated Mar. 17, 2004.
Order dated Nov. 25, 2003 in Civ. A. No. 03–2268 (*Nattermann* v. *Bayer* litigation).
Bayer's Opposition to Plaintiffs' Motion To Dismiss All Claims And Counterclaims Without Prejudice or, in the Alternative, Stay Proceedings Pending Reexamination (with Exhibits), filed Nov. 26, 2003.
Defendants' First Amended Answer And Counterclaims, filed Nov. 26, 2003.
Transcript of Hearing Held on Dec. 1, 2003 in Civ. A. No. 03–2268 (*Nattermann* v. *Bayer* Litigation).
Plaintiffs' Answer to First Amended Counterclaim, filed Dec. 23, 2003.
Letter from Bayer's Counsel to Honoroable Anita B. Brody dated Jan. 7, 2004, submitted in Civ. A. No. 03–2268 (with Exhibits).
Letter from Nattermann's counsel to Honorable Anita B. Brody dated Jan. 9, 2004, submitted in Civ. A. No. 03–2268 (with Exhibits).
Plaintiffs' Motion To Dismiss All Claims And Counterclaims Without Prejudice Or, In The Alternative, Stay Proceedings Pending Reexamination Of U.S. Pat. No. 5,565,527 (with Order and Exhibits), filed Jan. 16, 2004.
Letter from Bayer's counsel to Honorable Anita B. Brody forwarding Stipulated Protective Order and copy of Stipulated Protective Order, dated Jan. 21, 2004.
Transcript of Jan. 12, 2004 hearing in the Civ. A. No. 03–2268 (*Nattermann* v. *Bayer* litigation).
Bayer's Motion For Declaratory Judgment of Waiver of Plaintiff's Compulsory Counterclaims (with Exhibits), filed Jan. 26, 2004.
Order dated Jan. 29, 2004 in Civ. A. No. 03–2268 (*Nattermann* v. *Bayer* litigation).
Arakawa, Tsutomu et al., "Stabilization of Protein Structure by Sugars," Biochemistry, vol. 21: 6536–6544 (1982).
Berntorp, Erik, et al., "Hepatitis C Virus Transmission by Monoclonal Antibody Purified Factor VIII Concentrate," The Lancet, vol. 335: 1531–1532 (1990).
Bray, Gordon L., "Recent Advances in the Preparation of Plasma-Derived and Recombinant Coagulation Factor VIII," The Journal of Pediatrics: 503–507 (1990).

Tootill, E., "The Facts on File Dictionary of Biology," Revised and Expanded Edition, pp. 44; 293.

Kernoff, Peter B. A., "Hepatitis and Factor VIII Concentrates," Seminars in Hematology, vol. 25:2, Suppl. 1: 8–13 (1988).

Lee, James C. et al., "The Stabilization of Proteins by Sucrose." The Journal of Biological Chemistry, vol. 256: (14) 7193–7201 (1981).

Lusher, Jeanne M. et al., "Viral Safety and Inhibitor Development Associated With Factor VIIIC Ultra-Purified From Plasma in Hemophiliacs Previously Unexposed to Factor VIIIC Concentrates," Seminar in Hematology, vol. 27:2, Suppl. 2: 1–7 (1990).

Budavari, Susan et al. (eds.), "The Merck Index, An Encyclopedia of Chemicals, Drugs, and Biologicals," p. 1401 (1989).

Pierce, Glen F. et al., "The Use of Purified Clotting Factor Concentrates in Hemophilia, Influence of Viral Safety, Cost, and Supply on Therapy," JAMA, vol. 261:23, (1989).

Stryer, Lubert, "Biochemistry Third Edition," pp. 16–21 (1988).

A. Munoz et al., "A randomized hemodynamic comparison of intravenous amiodarone with and without Tween 80," *European Heart Journal*, vol. 9: 142–148 (1988).

Complaint for Patent Infringement filed by A. Nattermann & Cie GmbH et al. against Baxter Healthcare Corp. in the District Court for the District of Delaware (Apr. 11, 2003).

Answer and Counterclaim for Declaratory Judgment filed by Baxter Healthcare Corp. in the District Court for the District of Delaware (May 27, 2003).

Reply of Counterclaim filed by A. Nattermann & Cie GmbH et al. in the District Court for the District of Delaware (Jun. 18, 2003).

Defendants' Answer and Counterclaims filed by Bayer Corp. et al., in the District Court for the Eastern District of Pennsylvania (May 1, 2003).

Answer to Counterclaims filed by A. Nattermann & Cie GmbH et al. in the District Court for the Eastern District of Pennsylvania (May 21, 2003).

Defendants' Motion for Summary Judgment of Noninfringement (with attachments), filed by Bayer Corp. et al., in the District Court for the Eastern District of Pennsylvania (Oct. 10, 2003).

Memorandum in Support of Defendants' Motion for Summary Judgment of Noninfringement (with attachments), filed by Bayer Corp. et al., in the District Court for the Eastern District of Pennsylvania (Oct. 10, 2003).

Bayer Corporations's and Bayer Healthcare LLC's Motion for Leave to File Defendants' First Amended Answer and Counterclaims filed in the District Court for the Eastern District of Pennsylvania (with attachments) (Oct. 14, 2003).

Bayer Corporations's and Bayer Healthcare LLC's Memorandum in Support of Their Motion for Leave to File Defendants' First Amended Answer and Counterclaims filed in the District Court for the Eastern District of Pennsylvania (with attachments) (Oct. 14, 2003).

* cited by examiner

EX PARTE REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS INDICATED BELOW.

Matter enclosed in heavy brackets [ ] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

The patentability of claim **11** is confirmed.

Claim **1** is cancelled.

Claims **2–8, 10, 12** and **13** are determined to be patentable as amended.

Claim **9**, dependent on an amended claim, is determined to be patentable.

New claims **14–23** are added and determined to be patentable.

2. A solution as claimed in claim **[1]** *15*, wherein the amino acid is a natural amino acid.

3. A solution as claimed in claim **[1]** *15*, wherein the amino acid is a basic amino acid.

4. A *stabilized* solution **[**as claimed in claim **1**, which**]** *with factor VIII:C activity containing factor VIII:C, an amino acid or one of its salts or homologs and a detergent or an organic polymer, wherein the specific factor VIII:C activity is at least 1000 IU/mg and wherein the stabilized solution* contains arginine and glycine.

5. A solution as claimed in claim **[1]** *15*, wherein the concentration of the amino acid is 0.001 to 1 mol/l.

6. A solution as claimed in claim **[1]** *15*, which contains an organic polymer or a nonionic detergent.

7. A solution as claimed in claim **[1]** *15*, wherein the F VIII:C activity is derived (a) from human factor VIII in its form which occurs in plasma or (b) from a genetically engineered factor VIII:C or (c) from a homolog of (a) or (b).

8. A pharmaceutical containing a solution as claimed in claim **[1]** *14*.

10. A pharmaceutical **[**as claimed in claim **9,]** which contains *a stabilized solution with factor VIII:C activity containing factor VIII:C, an amino acid or one of its salts or homologs, a detergent or an organic polymer, and* a carbohydrate *wherein the specific factor VIII:C activity is at least 1000 IU/mg, and further containing pharmaceutically compatible, stabilizing or buffering substances.*

12. A stabilized solution **[**as claimed in claim **1]** *with factor VIII:C activity* containing *factor VIII:C,* an amino acid or one of its salts or homologs and an organic polymer, *wherein the specific factor VIII:C activity is at least 1000 IU/mg, and* wherein the amino acid is arginine or glycine and the organic polymer is polyethylene glycol.

13. A stabilized solution as claimed in claim **[1]** *15*, containing an amino acid or one of its salts or homologs and a detergent, wherein the amino acid is arginine or glycine and the organic detergent is polyoxyethylene sorbitan monooleate.

14. A stabilized solution with factor VIII:C activity containing factor VIII:C, an amino acid or one of its salts or homologs and a detergent or organic polymer, wherein the specific factor VIII:C activity is at least 2000 IU/mg.

15. A stabilized solution with factor VIII:C activity containing factor VIII:C, an amino acid or one of its salts or homologs, a detergent or organic polymer, and a carbohydrate, wherein the specific factor VIII:C activity is at least 1000 IU/mg.

16. A stabilized solution with factor VIII:C activity containing factor VIII:C, an amino acid or one of its salts or homologs, a detergent or organic polymer, and a carbohydrate, wherein the specific factor VIII:C activity is at least 2000 IU/mg.

17. A stabilized solution with factor VIII:C activity containing factor VIII:C, an amino acid or one of its salts or homologs, a detergent or organic polymer, and a carbohydrate, wherein the specific factor VIII:C activity is at least 3280 IU/mg.

18. A stabilized solution with factor VIII:C activity containing factor VIII:C, an amino acid or one of its salts or homologs, a detergent or organic polymer, and a carbohydrate, wherein the specific factor VIII:C activity is at least 2000 IU/mg and wherein the stabilized solution with factor VIII:C activity does not contain albumin.

19. A stabilized solution with factor VIII:C activity containing factor VIII:C, an amino acid or one of its salts or homologs, a detergent or organic polymer, and a carbohydrate, wherein after lyophilization and reconstitution, the specific factor VIII:C activity is at least 2000 IU/mg.

20. A solution as claimed in claim 7, wherein the factor VIII:C activity is derived from a genetically engineered factor VIII:C.

21. A stabilized solution with factor VIII:C activity containing factor VIII:C, an amino acid or one of its salts or homologs, a detergent or organic polymer, wherein the specific factor VIII:C activity is at least 1000 IU/mg and wherein the potency of the stabilized factor VIII:C solution is at least 200 IU/ml.

22. A stabilized solution with factor VIII:C activity containing factor VIII:C, an amino acid or one of its salts or homologs, a detergent or organic polymer, and a carbohydrate, wherein the specific factor VIII:C activity is at least 2000 IU/mg and wherein the potency of the stabilized factor VIII:C solution is at least 200 IU/ml.

23. A stabilized solution with factor VIII:C activity containing factor VIII:C, an amino acid or one of its salts or homologs and a detergent or an organic polymer, wherein the specific factor VIII:C activity is at least 1000 IU/mg and wherein the concentration of detergent is from 0.001 to 0.05% v/v.

* * * * *

JS 44 (Rev. 3/99)

CIVIL COVER SHEET

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

AVENTIS PHARMA S.A.

(b) County of Residence of First Listed Plaintiff *
(EXCEPT IN U.S. PLAINTIFF CASES)

* Plaintiff is a French corporation

DEFENDANTS

BAXTER HEALTHCARE CORP.

County of Residence of First Listed _____
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

(c) Attorney's (Firm Name, Address, and Telephone Number)

Steven J. Balick
Ashby & Geddes, 222 Delaware Avenue, 17th Fl.
P.O. Box 1150, Wilmington, DE 19899
(302) 654-1888

Attorneys (If Known)

Unknown

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

		DEF		DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4 ☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5 ☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6 ☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury—Med. Malpractice
- ☐ 365 Personal Injury—Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence
- Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☒ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce/ICC Rates/etc.
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes
- ☐ 890 Other Statutory Actions

V. ORIGIN (PLACE AN "X" IN ONE BOX ONLY)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing and write brief statement of cause. Do not cite jurisdictional statutes unless diversity.)

This is an action arising under the patent laws of the United States, 35 U.S.C. § 100, et seq.

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 DEMAND $ monetary relief CHECK YES only if demanded in complaint: JURY DEMAND: ☐ Yes ☒ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE Sleet DOCKET NUMBER 03-373-GMS

DATE October 16, 2006 SIGNATURE OF ATTORNEY OF RECORD Steven J. Balick

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

JS 44 Reverse (Rev. 12/96)

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS-44

Authority For Civil Cover Sheet

The JS-44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. (a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b.) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States, are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

III. Residence (citizenship) of Principal Parties. This section of the JS-44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section IV below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a) Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause.

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS-44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

AO FORM 85 RECEIPT (REV. 9/04)

United States District Court for the District of Delaware

Civil Action No. 06-636

ACKNOWLEDGMENT OF RECEIPT FOR AO FORM 85

NOTICE OF AVAILABILITY OF A UNITED STATES MAGISTRATE JUDGE TO EXERCISE JURISDICTION

I HEREBY ACKNOWLEDGE RECEIPT OF 1 COPIES OF AO FORM 85.

OCT 16 2006
(Date forms issued)

(Signature of Party or their Representative)

Dustin Frohlich
(Printed name of Party or their Representative)

Note: Completed receipt will be filed in the Civil Action